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ABBREVIATIONS

DCCR	Division of Cancer Control and Rehabilitation
HEW	Department of Health, Education, and Welfare
NCI	National Cancer Institute
NIH	National Institutes of Health

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BY THE U.S. GENERAL ACCOUNTING OFFICE

Report To The Honorable David R. Obey House Of Representatives

COMPLETED

020-006-00175-3

Dear Jake ORIGINAL

The Objectives Of The Cancer Control Program And The National Cancer Institute's Administration Of Program Contracts

R. Lesh 8-7-80

The cancer control program was established by the National Cancer Act of 1971 to rapidly transfer cancer advances from the research setting to general medical use. In implementing the program, the Institute conducts a wide range of activities, such as disseminating information, gathering statistics, and conducting education programs.

The Institute administers the program through grants, contracts, and interagency agreements awarded to State and local health agencies, medical centers, and others.

The Institute's administration of the award of and work under five cancer control contracts was weak. As a result, three of the completed contracts GAO reviewed fell short of their objectives.

HRD-80-57
JUNE 13, 1980

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Human Resources
Division

B-197753

The Honorable David R. Obey
House of Representatives

Dear Mr. Obey:

In your March 1, 1979, letter, you asked us to review certain aspects of the National Cancer Institute's (NCI's) cancer control program. In discussions with your office, we agreed to obtain information on the program's

--objectives;

--contract award and management;

--demonstration projects, including whether NCI attempts to encourage continuation of projects after Federal funding ceases;

--staffing; and

--advisory groups, including actions taken on advisors' recommendations.

On February 8, 1980, we briefed your staff on the results of our work. This report discusses the program's objectives, NCI's administration of cancer control contracts, the efforts to assure continuation of demonstration projects, funding and staffing levels, and advice provided by cancer control advisory groups and NCI's implementation of advisors' recommendations.

SCOPE OF REVIEW

We analyzed the legislative history of the cancer control program to determine its mission and objectives. We discussed these issues with NCI officials, including the Acting Director of the Division of Cancer Control and Rehabilitation (DCCR) and the former Director. We obtained data from NCI on the funding and staffing levels for NCI and DCCR--from fiscal year 1975 when DCCR was formed, through fiscal year 1979--and determined the proportion

of funds and staff assigned to the cancer control program. We identified the advisory groups for the cancer control program and discussed the program's mission, objectives, accomplishments, and future with current and former chairmen of these groups. Also, we analyzed the groups' recommendations and determined NCI's actions to implement them.

We made a detailed examination of five contracts to determine (1) how NCI awarded and managed them and (2) whether NCI received the product(s) specified. Because of your interest in cancer control contracts awarded to the University of Louisville Foundation, Inc., and the Texas Chest Foundation/East Texas Chest Hospital at Tyler, Texas, our review included NCI contracts with these institutions. The other three contracts--with the University of Arizona, the Illinois Cancer Council, and the New York State Department of Health and Health Research, Inc.--were chosen because they represented major NCI efforts in the fields of breast, head and neck, and cervical cancer, respectively. The contracts we reviewed were awarded between June 1974 and September 1975.

Our review of individual contracts included examining the information in NCI's contract files at its offices in Bethesda, Maryland, and discussing the results of the contracts with NCI officials and advisors. We did not do any review work at contractor locations because most of the information we needed was in NCI files. Also, work at these locations would have required much more time. Our conclusions on NCI's procedures used in awarding and managing contracts and the ultimate result of the projects are based on these analyses and discussions. At the conclusion of our work, NCI reviewed a copy of our draft report. Where appropriate, we incorporated NCI's comments in the report. The full text of those comments appears as appendix VI.

This letter contains a summary of the results of our review. A more detailed discussion of our findings is contained in appendixes I to IV.

LEGISLATIVE BACKGROUND AND PROGRAM OBJECTIVES

The origin of NCI's cancer control program can be traced to the National Cancer Institute Act of 1937 (Public Law 75-244), which gave NCI responsibility for conducting research to prevent, diagnose, treat, and control cancer in humans. However, not until the Congress enacted the National Cancer Act of 1971 (42 U.S.C. 282) 1/ was a separate cancer control program established. Under this legislation, the Director of NCI was to establish programs for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer.

The cancer control program was described in the legislative history of the 1971 act as a means of "bridging the gap" between research and general medical application. The act authorized the cancer control program but it did not define the specific activities NCI was to undertake. The act's legislative history shows that NCI was to develop an aggressive and coordinated cancer control program to demonstrate the application of recent research discoveries as rapidly as possible and communicate these findings to practitioners for application. In addition to emphasizing the communication of research findings, the legislative history discussed other activities that NCI should include in the cancer control program.

According to NCI officials and current and past advisors to the control program, the scientific community and the Congress thought, at the time the 1971 act was enacted, that many research advances existed which could affect cancer, but these advances were not being disseminated and used. The cancer control program was intended to bridge this gap. However, the individuals said this assumption proved to be incorrect because few cancer advances existed that the medical community was not using.

The 1971 act, as it pertains to the cancer control program, was subsequently amended in 1974 and 1978 and added

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1/The National Cancer Act of 1971 established a National Cancer Program and required the Director of NCI to plan and develop an expanded, intensified, and coordinated cancer research program.

requirements for NCI to conduct programs in diagnosing uterine cancer (i.e., Pap tests), and demonstration and education programs.

Division of Cancer Control and Rehabilitation

Originally, NCI administered the cancer control program from the NCI Director's office. In September 1974, NCI formed the Division of Cancer Control and Rehabilitation, which is now responsible for program administration. DCCR has no inhouse cancer control program. It carries out the program through grants, contracts, and interagency agreements awarded to State and local health agencies, medical centers, NCI's recognized comprehensive cancer centers, teaching institutions, community hospitals, professional societies, nonprofit organizations, and other Federal agencies. In fiscal year 1979, DCCR had a staff of 42 employees and a budget of about $70 million. About $45 million of DCCR's budget was obligated for contracts.

In October 1979, the NCI Director announced that DCCR would be abolished and replaced by a Division of Resources, Centers, and Community Activities. This division would be responsible for all the activities formerly assigned to DCCR plus other NCI activities, such as the cancer research centers, construction, education, and training programs. According to the proposal for reorganization being circulated for approval, the purpose of the reorganization is to make NCI programs more responsive to needs in the areas of prevention and transfer of research findings. As of March 1980, NCI was waiting for the Secretary of Health, Education, and Welfare to approve this reorganization.

NCI PRACTICES WERE UNSOUND IN AWARDING SOME CANCER CONTROL CONTRACTS

About $216 million (72 percent) of the $302 million allocated for the cancer control program in the past 5 fiscal years was obligated for contracts. We reviewed five contracts that amounted to about $10.3 million. These contracts were awarded to the universities of Arizona and Louisville, the Illinois Cancer Council, the New York State Department of Health and Health Research, Inc., and the Texas Chest Foundation/East Texas Chest Hospital. The Louisville and

Texas contracts were to develop model programs for preventing cancer caused by workers' exposure to vinyl/polyvinyl chloride and asbestos, respectively. The Arizona, New York, and Illinois contracts dealt with controlling breast, cervical, and head and neck cancer, respectively.

Our review showed that NCI did not award the contracts in accordance with the Department of Health, Education, and Welfare (HEW) 1/ contracting procedures or sound management practices. NCI significantly increased the amounts authorized for the Louisville and New York contracts by a total of about $3.6 million without revising plans for the projects.

In the preaward reviews of the proposed contracts, review groups identified many problems and made recommendations for correcting them. For the Louisville and New York contracts, we found no evidence that DCCR took any action to implement the reviewers' recommendations.

Many cancer control grants and contracts are for demonstration projects which by design are to continue in the localities after Federal funding ends. NCI expected that the projects initiated under all five of the contracts we examined would be continued. DCCR has never done a study to determine the number of demonstration projects that are continued by localities, and does not know the extent to which demonstration projects are continued by localities after Federal funding stops.

INEFFECTIVE MANAGEMENT OF CANCER CONTROL CONTRACTS BY NCI

NCI did not effectively manage four of the five contracts we examined. It failed to correct problems found by advisors reviewing the contracts. Contractors did not perform tasks specified in the contracts, and project

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1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

officers failed to bring problems to the attention of contracting officers so that corrective actions could be taken. In our opinion, this contributed to three contracts not fully achieving the intended objectives. While the workload of some project officers may have contributed to ineffective contract management, we believe the lack of cooperation between DCCR project officers and NCI contracting officers was the main reason that these projects failed to fully achieve their objectives.

Since our review was limited to five contracts (awarded before 1976), we cannot say whether the deficiencies we found are widespread. However, in the last 5 years other groups have reviewed NCI's contracting procedures. Some of the reviews included cancer control contracts, while others did not. These reviews identified many weaknesses in NCI's contracting operations. HEW's Inspector General found similar deficiencies in NCI's overall contract administration, and the Chairman of the Cancer Control Merit Review Committee said that there are problems similar to those we found in about half of NCI's cancer control contracts. The Inspector General's office is reviewing NCI's efforts to correct contracting deficiencies, including a review of cancer control contracts.

STAFF AVAILABLE FOR THE PROGRAM HAS NOT KEPT PACE WITH FUNDING

During the last 5 fiscal years, the funds obligated for the cancer control program have increased by 38 percent, but the staff authorized has increased by only 2 percent. DCCR has had difficulty in obtaining staff for the program, and 12 percent of the authorized positions remained vacant in fiscal year 1979. An NCI official estimated that all of the vacant positions were for professional personnel, who have been difficult to obtain because of the salary difference between the Federal and private sectors. DCCR has hired experts to try and overcome its shortage of professionals.

DCCR HAS ACTED TO IMPLEMENT RECOMMENDATIONS MADE BY POLICY ADVISORS

DCCR receives policy advice on the cancer control program from three advisory groups--the President's Cancer

Panel, the National Cancer Advisory Board, and the Cancer Control and Rehabilitation Advisory Committee. Of these groups, the latter has provided most of the advice and recommendations to DCCR. DCCR has taken adequate action to implement the Committee's recommendations.

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We hope the information in this report is responsive to your needs. As agreed with your office, we will not release this report for 30 days to other interested parties unless you have approved its release or make its contents public.

Sincerely yours,

Gregory J. Ahart
Director

LEGISLATIVE BACKGROUND AND OBJECTIVES OF THE CANCER CONTROL PROGRAM

The origin of the National Cancer Institute's (NCI's) cancer control program began with the 1937 National Cancer Institute Act. However, a specific authorization for a cancer control program did not occur until the National Cancer Act of 1971 was enacted, authorizing NCI to establish cancer control programs in cooperation with States and health agencies to rapidly transfer research results into general medical application. The 1971 act did not specify the activities NCI was to undertake to implement the cancer control program, although the act's legislative history provided guidance in this area. Legislation enacted in 1974 and 1978 specified activities for NCI to include in the program.

The objectives of cancer control are different than those of cancer research. Cancer research seeks to find the means for combating cancer, whereas cancer control seeks to identify, test, evaluate, and promote the means that are found.

LEGISLATIVE BACKGROUND OF THE CANCER CONTROL PROGRAM--1937 to 1971

The origin of NCI's cancer control program began with the National Cancer Institute Act of 1937 (Public Law 75-244), which gave NCI responsibility for conducting research to prevent, diagnose, treat, and control cancer in humans. The 1937 act did not specify the activities NCI was to undertake to implement its control program. However, the act's legislative history shows that NCI was to purchase radium for use in the study and treatment of cancer; make grants-in-aid to schools, clinics, hospitals, laboratories, institutions, and scientific investigators for cancer research; and cooperate with State health departments and boards for the prevention, control, and eradication of cancer within the States. Subsequent amendments to NCI's legislation contained no discussion of cancer control

program activities until the Congress enacted the National Cancer Act of 1971 (42 U.S.C. 282). 1/

In July 1971, the Senate passed S. 1828. A compromise version of this bill ultimately became the National Cancer Act of 1971. Regarding cancer control, the Senate bill authorized NCI to cooperate with State health agencies in the prevention, control, and eradication of cancer, but did not authorize NCI to establish a separate cancer control program to accomplish this.

In November 1971, the House passed its version of the National Cancer Act (H.R. 11302). In a report by the House Committee on Interstate and Foreign Commerce on H.R. 11302, the Committee stated that it was very disturbed to find in its study of the cancer problem that identifiable funding for cancer control programs ended with fiscal year 1970 and that a number of activities (the Committee did not specify the activities), previously supported through these programs, have in one way or another been terminated or allowed to lapse. The Committee further stated

> "Disease control programs in cancer and other areas have long been a part of the public health scene, and their importance is incontrovertible, for they are a means of bringing into general medical applications the most practical fruits of research in terms of improved methods of treatment and control."

For States and other public or nonprofit organizations to once again receive funding for cancer control activities, the House Committee included in its bill the authority for NCI to establish programs in cooperation with State and other health agencies for the prevention, control, and eradication of cancer. H.R. 11302 authorized NCI to establish a cancer control program. According to the Committee, the purpose for this specific authorization was to ensure that "funds intended to help in the attack on cancer are not diverted."

1/The National Cancer Act of 1971 established a National Cancer Program and required the Director of NCI to plan and develop an expanded, intensified, and coordinated cancer research program.

APPENDIX I

In December 1971, the House and Senate conferees agreed to a compromise version of S. 1828. This version of the Senate bill closely followed the text of H.R. 11302, including a specific authorization for NCI's cancer control program. On December 23, 1971, the President signed into law S. 1828, which became Public Law 92-218, "The National Cancer Act of 1971." Section 409 of the act contained an authorization for NCI's cancer control program and states:

> "* * * (a) The Director of the National Cancer Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer."

Section 409 also authorized funds to carry out the program.

PROGRAM INTENT, GOALS, AND ACTIVITIES

The 1971 act did not discuss the intent of the Congress in authorizing the cancer control program or the activities NCI was to undertake in implementing it. The Senate did not address the issue, and we determined congressional intent from the 1971 report by the House Committee on Interstate and Foreign Commerce on H.R. 11302. According to the section of the report which discussed cancer control, the Committee saw an important role for NCI in "bridging the gap" between research and general medical application. The report stated that, once the effectiveness of research findings could be demonstrated to the satisfaction of the scientific community, these results should be communicated to medical practitioners quickly. NCI was to develop an aggressive and coordinated cancer control program to demonstrate the application of recent research discoveries as rapidly as possible, using whatever community resources were available, and communicate these findings to practitioners, who could apply these findings. According to the House Report, the following activities were to be included in NCI's cancer control program:

--Collecting, analyzing, and disseminating all data useful in the prevention, diagnosis, and treatment of cancer.

--Prevention (the elimination from the external and internal environment of chemical and other agents that cause or promote cancer).

--Pap tests for cervical cancer.

--Breast checks and oral examinations.

--Training for personnel in cancer.

--Gathering of cancer statistics.

--Cancer treatment (limited to demonstrations of new techniques or methods).

--Diagnosis.

According to the acting and the former directors 1/ of DCCR, the acting Chairman of the President's Cancer Panel, 2/ and the chairman of the National Cancer Advisory Board, the Cancer Control and Rehabilitation Advisory Committee, and the Cancer Control Merit Review Committee, at the time the National Cancer Act of 1971 was enacted, the scientific community and the Congress thought (1) that many research advances existed that could impact on cancer and (2) these advances were not being disseminated to the medical community to use on cancer victims and, as a result, were "on the shelf." NCI's cancer control program was to bridge this gap between research advances and application of the research by the medical community.

However, according to the acting and former directors of DCCR and the chairmen of the Panel, Board, Cancer Control and Rehabilitation Advisory Committee, and Cancer Control Merit Review Committee, the assumption that a significant number of cancer research advances existed that were not being used proved to be incorrect. These

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1/The former director of DCCR is now Associate Director for Medical Applications of Cancer Research, NCI. She served as Director of DCCR from September 1974 to April 1979.

2/We discussed the cancer control program with the acting Panel Chairman in October 1979. He served as the Panel's Chairman from July 1972 to February 1978 and was acting chairman from February 1978 to December 1979. In December 1979, a new Chairman was appointed. Since he was recently appointed to this position, we did not interview him.

officials told us that, in reality, very few cancer advances existed which the medical community was not using. We asked NCI to provide a list of cancer research advances that were not widely used before the cancer control program was established, but NCI did not furnish such a list.

In commenting on our draft report, NCI said that there were research advances that required dissemination in 1971, that there were research advances that require dissemination in 1980, and NCI anticipated additional research advances as long as there is a National Cancer Program. NCI provided two examples of advances that needed to be disseminated or put into practice--the identification of smoking as a major cause of lung cancer and the development of exfoliative cytology.

The 1971 act, as it pertains to NCI's cancer control program, was amended in 1974 by section 107 of the National Cancer Act Amendments of 1974 (88 Stat. 358) and in 1978 by section 236 of the Community Mental Health Centers Act Amendments (92 Stat. 3423). The 1971 act required the Director of NCI to conduct control programs with State and other health agencies in the diagnosis, prevention, and treatment of cancer. The 1974 amendments continued this requirement, but added a requirement that NCI conduct trial programs to diagnose uterine cancer (i.e., Pap tests). The 1978 amendments contained the current authorization for the cancer control program. Section 236 of the 1978 amendments specified demonstration and education as types of programs to be established and added detection, diagnosis, prevention, treatment, rehabilitation, and counseling as objectives for these programs. The Congress added three detailed directives to increase the effectiveness of the cancer control program. The first of these directives called for locally initiated education and demonstration programs to transmit research results and to disseminate information. The second directive required specific education and demonstration programs for health professionals in methods of early cancer detection, for identifying individuals with a high risk of developing cancer, and for improving patient referral for early diagnosis and treatment. The third directive called for the demonstration of methods for the efficient dissemination of information to the public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

Goals of the cancer control program

Before implementing the National Cancer Program, NCI held a series of planning conferences in 1971 and 1972 attended by 250 scientists. The scientists formed a group--Working Group 8--to establish the goals and objectives of the cancer control program. In June 1975, the Group issued its report proposing that the cancer control program be a distinct entity, separate from cancer research because, in the Group's opinion, cancer research seeks to find the means for combating cancer, whereas cancer control seeks to reduce the incidence, mortality, and morbidity from cancer by identifying, testing, evaluating, and promoting the means that are found. The Group said that the following activities were appropriate to implement this goal--prevention, screening and detection, diagnosis and pretreatment evaluation, treatment, rehabilitation, and continuing care. The cancer control program has emphasized these areas. In fiscal year 1979 NCI said it was conducting a multifaceted cancer control program focused on:

--Identifying, evaluating, and planning the application of innovative, practical methods of cancer control.

--Developing demonstration programs to promote the use of effective cancer control methods by the Nation's health professionals.

--Developing training resources for educating health professionals in the use of cancer control interventions.

--Developing methods of encouraging beneficial attitudes and life styles as they relate to the control of cancer with emphasis on hard-to-reach populations, such as minority groups and blue collar workers.

--Providing mechanisms for organizing the Nation's resources for an effective, coordinated attack on specific cancer control problems.

Examples of the types of projects NCI supports in the cancer control program are hospices, and studies on pain management, psychosocial impact of cancer, and radiotherapy practices.

ADVISORS HAVE MIXED OPINIONS ON THE CANCER CONTROL PROGRAM AND ITS FUTURE

We discussed the accomplishments of the cancer control program and its outlook for the future with the former Chairmen of the President's Cancer Panel, and the Cancer Control and Rehabilitation Advisory Committee, and the current Chairmen of the National Cancer Advisory Board, the Cancer Control and Rehabilitation Advisory Committee, and the Cancer Control Merit Review Committee. As discussed further in appendix IV, these groups provide advice to the cancer control program. They had mixed opinions on the program's accomplishments.

Four of the five said that the cancer control program was worthwhile and should be continued. The former Chairman of the Cancer Control and Rehabilitation Advisory Committee said the areas that showed the program's accomplishments were cervical cancer screening, breast cancer demonstration projects, the Cancer Information Service, the asbestos education program, and the community-based cancer programs (programs to coordinate all cancer activities and services in a community). The current Chairman of the Committee said the accomplishments were the community-based programs and the Cancer Information Service. With the exception of the Cancer Information Service, the current Chairman of the National Cancer Advisory Board cited the same accomplishments as the former chairman of the Cancer Control and Rehabilitation Advisory Committee. In addition, he cited hospices; pain management for cancer patients; studies on effects of exposure to diethylstilbestrol, radiotherapy practices, and psychosocial impact of cancer; state of the art consensus conferences; cancer rehabilitation programs; and funding for training of oncology nurses.

The Chairman of the Cancer Control Merit Review Committee 1/ said the program had accomplished little that the medical community would not have done anyway and had not increased the body of knowledge needed to control cancer. He believed that the only part of the control program worth continuing was the community-based programs, but these programs

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1/This official resigned as the Chairman after our meeting with him.

needed better NCI management. NCI officials discussed the program's accomplishments with the Chairman after our meeting with him. NCI officials told us that the Chairman intended to convey that the program focused on procedures that were already being performed, and that the program helped disseminate them more rapidly, but that for some of them, dissemination would have happened sooner or later.

The former Chairman of the President's Cancer Panel offered no specific program accomplishments. He said that the accomplishments were in generating activity in proper cancer control areas and in getting known techniques put into use.

In terms of future funding levels and areas of emphasis for the control program, the chairmen's views were also mixed. However, none said the program suffered from a lack of funds. The chairmen's views concerning future direction of the program could be summarized as follows:

--Only fund community-based programs and put remaining funds into basic cancer research.

--Continue funding the program at the current fiscal year 1979 level.

--Emphasize prevention activities and let other projects expire and reduce the funding level.

In addition to the areas mentioned above, the Chairman of the National Cancer Advisory Board recommended that NCI evaluate the impact of existing methodologies on cancer morbidity and mortality.

NCI officials believed that the cancer control program had many significant accomplishments. They listed 57 items, such as

--techniques for measuring, monitoring, and lowering mammographic radiation;

--task forces on asbestos exposed workers and diethylstilbestrol exposed offspring;

--prototype clinical oncology programs for community hospitals to improve cancer management;

--development of rehabilitation and outreach programs; and

--education programs for health safety of workers exposed to carcinogens.

We did not assess the effect that cited accomplishments had on controlling cancer.

NCI COMMENTS AND OUR EVALUATION

In the draft report provided to NCI for comment, we included a recommendation that the Congress, possibly through oversight hearings, decide what the objectives of the cancer control program should be and what level of effort is needed to accomplish these objectives. NCI disagreed with our recommendation.

In February 1980, we discussed our draft report with staff of the Subcommittee on Health and Scientific Research, Senate Committee on Labor and Human Resources, and the Subcommittee on Health and the Environment, House Committee on Interstate and Foreign Commerce. Both subcommittees were working on amendments to the Public Health Service Act (S. 988 and H.R. 6522, respectively), which include language on the cancer control program. The Subcommittee on Health and Scientific Research held hearings on S. 988 and was in the process of "marking up" the bill. The Subcommittee on Health and the Environment held hearings on February 25, 1980, and raised several questions regarding the cancer control program.

Since the congressional committees have recently held hearings on the program, and we provided the information from our review to the appropriate legislative committees for their use in considering the bills, we have deleted our proposed recommendation from the final report. In addition, we deleted sections from the report that pertained to our proposed recommendation.

NCI'S ADMINISTRATION OF FIVE CANCER CONTROL CONTRACTS HAS BEEN WEAK

NCI's administration of the five cancer control contracts we reviewed was weak in both awarding of contracts and postaward management. In our opinion, the inadequate contract administration is attributable to heavy caseloads for some project officers, lack of cooperation between project officers and contract officers, and failure to use prudent management practices. As a result, the benefits from three completed contracts were substantially less than expected. Although our review of five contracts is not a sufficient basis on which to characterize programwide contract administration, we noted that other reviews made of contracting in NCI--some of which included the cancer control program--have indicated contract administration problems. Also, the Chairman of the Cancer Control Merit Review Committee (a committee which reviews ongoing contracts for project effectiveness), told us that he believes problems similar to the ones we found exist in about 50 percent of NCI's cancer control contracts.

In response to a May 1978 Department of Health, Education, and Welfare (HEW) 1/ Inspector General's audit report, an action plan to correct NCI contracting deficiencies was prepared. This plan was approved on May 24, 1978, by the HEW Assistant Secretary for Management and Budget. The Inspector General's staff is now reviewing how well the plan is being implemented and whether it is overcoming deficiencies, such as the ones described in our report.

Of the $302 million allocated by NCI for the cancer control program in the last 5 fiscal years, about $216 million (72 percent) was obligated for contracts. The five contracts we reviewed amounted to about $10.3 million.

1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

NCI USED QUESTIONABLE PRACTICES IN AWARDING SOME CANCER CONTROL CONTRACTS

NCI's contracting procedures, (referred to as the Orange Book), 1/ require that, before a contract is awarded, a project plan must be prepared. The procedures state that major project changes require amendments to the project plan. NCI did not adhere to this requirement before awarding some cancer control contracts. As a result, NCI awarded contracts for amounts greatly exceeding that approved in project plans. Further, NCI has failed to correct some deficiencies found by preaward review groups.

Revised project plans

The Orange Book states that, when the final negotiated cost of a contract is to be significantly different from the original project plan, the project plan must be revised. Further, any contract modification that increases funding by $50,000 or more, or by 25 percent or more above the funding levels for the project plan period, requires an amendment to the project plan. Our review indicated that NCI did not adhere to these requirements for two of the five contracts we examined.

In the contract awarded to the University of Louisville to develop a model program for the early detection and prevention of liver cancer caused by worker exposure to vinyl/polyvinyl chloride, the estimated amount of the project as noted in the project plan was $880,000. However, the negotiated amount of the contract was about $2.8 million--more than three times the original estimate.

NCI contends that the project plan was revised and the increase in costs was properly approved. NCI advised us that the responsible officials--with the exception of the former Director, DCCR--attended a meeting during which the project plan revision was prepared. The officials who attended this meeting and later signed the revision document were provided a proposal containing the increased cost estimates. Because

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1/The Orange Book was implemented by NCI in January 1973. It establishes minimum requirements for project review, details procedures for documenting contract awards, and specifies requirements for committee review to be followed by all NCI groups.

the former Director, DCCR, was out of the country at the time of the meeting, she did not know of the increased project cost. When she signed the plan revision document as the approving official, the portion of the document that was to show the revised cost estimate was blank. She told us she did not know that she had approved a contract award for $2.8 million until she later read about it in a news release. NCI does not agree that it failed to follow procedures for revising the project plan. It characterizes the situation as a clerical error. We believe that, when an approving official signs a document which authorizes the expenditure of $2.8 million of Federal funds without knowing how much of an expenditure is being approved, it is more than a clerical error.

In a contract awarded to the New York State Department of Health and Health Research, Inc., to conduct a cervical cancer screening demonstration program, the estimated amount of the contract as stated in the project plan was $750,000. However, the negotiated amount of the contract was about $2.5 million. NCI failed to prepare a revised project plan which specifically mentioned the large increase in the New York contract. NCI did prepare a revised project plan that covered the entire cervical cytology screening program involving many contracts. However, the revision showed a decrease in the estimated costs for the initial year of the total program, and makes no mention that the annual cost of the New York contract was being more than tripled from the costs approved in the original project plan for the New York project.

NCI has failed to correct deficiencies found by preaward review groups

As stated previously, NCI has a system whereby both NCI staff and advisory groups review proposed cancer control projects before contract award. For the Louisville and New York contracts, our review showed that these groups identified many problems in the proposed contracts and made nine recommendations to correct them. However, we found no evidence that DCCR took any action to implement the recommendations before awarding the contracts. The following paragraph discusses the problems found and recommendations made in the preaward review of the Louisville contract.

In May 1975, the Cancer Control Intervention Programs Review Committee found three deficiencies that it said should be corrected before the contract was awarded. These deficiencies pertained to the (1) absence of an individual to

conduct the health education program for plant workers and their families on the hazards of vinyl/polyvinyl chloride and the lack of a strong participatory role for the educator, (2) lack of coordination and cooperation among various parties in the program, and (3) lack of a system for locating about 1,500 former plant employees. We found no evidence that DCCR required the applicant to correct these problems before award of the contract. While the coordination problem was later resolved, we found no evidence that the problem in locating former employees was ever corrected, as the problem continued to be reported by advisory groups that reviewed the contract while the project was ongoing. The contractor did take action to hire a health educator for the program in September 1975; however, that person was not able to fulfill the role needed for the program and was replaced. A new health educator was not hired until November 1976--15 months after the contract was awarded. In commenting on our draft report, NCI agreed that no action was taken on these deficiencies before the award of the Louisville contract. However, NCI said these deficiencies represented contracting practices that occurred in 1974 and 1975, which have been corrected.

NCI is unaware of the extent that demonstration projects are continued

In fiscal year 1977 Senate appropriations hearings, NCI stated that cancer control funds are used as "seed money" for prototype studies and not for general health care delivery. Also, NCI said that projects are expected to ensure a means of self-support after the grant or contract period. In this regard, many of DCCR's grants and contracts are classified as demonstration projects. According to the Acting Director of DCCR, their purpose is to demonstrate, in a field setting, a new research finding or technique, and after Federal funding of the demonstration project ends, the local community is to decide whether to continue the project.

The five contracts we reviewed were classified as demonstration projects. According to the acting and former directors of DCCR, the Division does not normally attempt to require contractors to inquire into efforts being made to continue projects after Federal funding has ended. These officials said that DCCR has never done a study to determine how many demonstration projects have continued. Consequently, DCCR does not know the extent to which demonstration projects are continued by localities after Federal funding ends.

APPENDIX II

NCI HAS NOT EFFECTIVELY MANAGED CANCER CONTROL CONTRACTS

NCI did not effectively manage four of the five contracts we examined. It failed to (1) correct problems found by advisors that reviewed the contracts and (2) require contractors to complete required tasks. In our opinion, this contributed to three of the contracts not fully achieving their intended objectives. The project officers' caseloads may have contributed to the inadequate management of these contracts. However, we believe a more significant reason was the failure of the principal parties responsible for managing contracts--project and contracting officers--to cooperate in guiding projects toward successful completion.

NCI has not implemented recommendations of postaward review groups

In addition to preaward reviews, DCCR established in 1975 a system in which each cancer control contract is reviewed midway through the life of a contract by a merit review committee. In 1978, NCI established a separate committee--the Cancer Control Merit Review Committee--to perform this function. 1/ When the merit review is completed, the executive secretary of the committee prepares a summary that assesses the strengths and weaknesses of the contract and makes recommendations to the DCCR Director and Chief of NCI's Control and Rehabilitation Contracts Section on future actions. Also, some DCCR project officers and specialists make site visits to contractor facilities to monitor contractors' performance.

In addition, DCCR stated that the project officer has the major responsibility for managing the contracts' technical merits. In 1971, HEW published a guide, "The Negotiated Contracting Process," for project officers to follow in performing this function. In 1978, the National Institutes of Health (NIH) published a similar document called "A Guide for Project Officers." In July 1978, the Director of NCI

1/Before the Cancer Control Merit Review Committee was established, the merit review function was performed by the Cancer Control Intervention Programs Review Committee and the Cancer Control Community Activities Review Committee. We reviewed the advice provided by these committees when they functioned as merit review groups.

established a policy that required each project officer to prepare a semiannual report for submission to his/her supervisor indicating the technical progress of each contract. A copy of the report was to be submitted to the cognizant contracting officer for appropriate action. The Director stated that, in preparing the reports, project officers were to stress the issues discussed in "The Negotiated Contracting Process," covering such areas as management, level of performance, need for approvals to change contract terms, and the need for site visits.

HEW's "The Negotiated Contracting Process" emphasizes the need for project and contracting officers to cooperate in managing the contractors' performance. It states that, if performance is not proceeding satisfactorily or if problems are anticipated, the project officer should notify the contracting officer of the causes and the recommended course of action from a technical standpoint. Also, it stresses the need for immediate notification to assure that the contracting officer takes appropriate action to protect the Government's rights under the contract.

"The Negotiated Contracting Process" also states that no one can direct, or should request, the contractor to do anything that is not expressed as a term, condition, or provision of the contract. The HEW guidelines further state that the agent for action is the contracting officer and that the project officer is to monitor a contractor's performance closely and identify potential problems that threaten performance so that remedial measures may be taken.

NIH's "A Guide for Project Officers" emphasizes the importance of written communication between the project officer, contracting officer, and contractor. It states "unwritten understandings can result in serious contract and legal problems."

We reviewed the reports filed by the various merit review committees and the site visit teams for the five contracts we examined to determine DCCR's actions to correct problems and implement reviewers' recommendations. For the Louisville, Tyler, and Illinois Cancer Council contracts, we determined that the review groups identified 52 problems and made 43 recommendations to DCCR applicable to the contracts. These problems and recommendations dealt with such issues as contract tasks not being done, data collection problems, low levels of patient participation, technical deficiencies in

project design and performance, poor coordination among various parties, and failure to emphasize key tasks.

DCCR told us that it took action to implement all 43 recommendations made by the various review groups and site visit teams and provided us with memorandums, which DCCR considered to be evidence of its actions. Our review showed that DCCR's actions consisted of verbally informing the contractors of the review groups' recommendations and sending copies of the review groups' reports to the contractors. We found no evidence that DCCR ever directed the contractors in writing to implement the review groups' recommendations, nor was there any evidence to show why the recommendations should not be implemented. Thus, NCI left it up to the contractors to decide what recommendations to implement.

NCI advised us that sufficient followup was taken to determine that the contractors were taking steps to correct deficiencies. Again, we found no documentation to indicate contractor action. NCI believes this is more a failure of documentation rather than a failure to obtain action and represented past, rather than current, practices. However, we found nothing in NCI's procedures or practices to indicate that review groups' recommendations are handled differently from the manner we found in the contracts we reviewed.

We discussed this with the Chairman of the Cancer Control Merit Review Committee. He said that his Committee also found that DCCR apparently does little to implement the recommendations made by the Committee. In his opinion, DCCR's failure to act on the reviewers' recommendations made merit review a waste of time. When NCI asked the Chairman of the Cancer Control Merit Review Committee about this statement, he said, according to NCI, that his committee never received information concerning implementation of its recommendations and, therefore, had little basis to evaluate the matter. He also said this lack of information was a source of frustration.

According to the Chief of NCI's Control and Rehabilitation Contracts Section, one reason for contracting officers' failure to direct contractors to implement the recommendations of advisory groups is that DCCR project officers fail to notify the contracting officers of contractors' poor performance and to develop, with the contracting officers, a course of action to improve contractor performance. For example, in the Tyler contract, the project officer was

informed by site visitors of problems in the contractor's performance as early as 3 months into the contract period. However, the contracting officer at that time was not informed of the problems. The subsequent contracting officer only learned of problems when the merit review was performed--33 months after the contract began.

We discussed the management of cancer control contracts with the Chief of NCI's Control and Rehabilitation Contracts Section. He cited a lack of cooperation between the DCCR project officers and the NCI contracting officers. He could recall few instances where the project officers brought problems to the attention of the contracting officers for resolution. In his opinion, this situation has improved recently.

As discussed on page 15, NCI now has a system that requires each project officer to prepare a semiannual report on the technical progress of each contract. We examined 108 of these reports prepared from January to August 1979. We found that the reports provided mainly a summary of the progress of each contract, with 20 of the 108 reports (18 percent) discussing problems in performing the contracts. The Chief of the Control Contracts Section said that in the past he could recall only a few instances in which the reports identified any problems. The Acting Director of DCCR said that recently he had established a format for project officer reports, which he believes will identify weaknesses in contractor performance.

In a memorandum, the former Director of DCCR stated that the mechanisms for the interaction between the contracting and project officers did exist. In response to our inquiry, she advised us that the mechanisms were established by the start of fiscal year 1975. She said these mechanisms consisted of the Chief of the Control and Rehabilitation Contracts Section attending meetings of the DCCR Executive Committee. Also, the staff of the Control and Rehabilitation Contracts Section attended preaward and merit review committee meetings, planning sessions, and project plan reviews. She added that the NCI contracting officers were encouraged to attend review sessions, advisory committee meetings, and meetings with contractors and to make site visits with project officers. Finally, she said that she had almost daily communication with the Chief of the Contracts Section to discuss technical and contracting issues.

While the mechanisms for cooperation between the project and contracting officers may have existed in DCCR, they apparently did not work. The large caseload of both grants and contracts assigned to some project officers may have contributed to the lack of cooperation and coordination. For fiscal years 1975-79 the number of active grants and contracts was as follows:

Fiscal year	Total grants	Total contracts	Total grants and contracts
1975	28	240	268
1976	59	251	310
1977	77	248	325
1978	83	198	281
1979	100	176	276

The project officers' caseloads vary significantly. Twelve of the professional staff have project officer responsibilities for grants and contracts. Caseloads vary from 3 to 44 projects, according to an October 1979 program list. In addition to being the project officer for 30 projects, one staff member also had to carry out the responsibilities of a branch chief. NCI commented that lumping grants and contracts together is misleading because grants require less monitoring. Also, NCI said that managing many contracts on the same project required less work than managing an equal number of contracts with different work scopes.

Contractors have often not accomplished tasks specified in contracts

Of the five contracts we examined, the period for performance had ended for three of them at the time of our review. The following table shows that these contracts called for 33 tasks to be accomplished at a cost of $7.8 million. As shown in reports of the Cancer Control Merit Review Committee and through discussions with DCCR project officers, the contractors did not accomplish 13 of the tasks.

Contract	Tasks to be accomplished	Tasks not accomplished	Amount of award (note a)	Amount paid by NCI
			(millions)	
Louisville	11	4	$2.8	$2.4
New York	9	7	2.5	1.5
Tyler	13	2	2.5	2.1
Total	33	13	$7.8	$6.0

a/Original award plus any modifications that added to the award amount.

The differences between the amounts awarded and the payments made on the contracts do not represent adjustments made because contractors failed to accomplish certain tasks. The following example explains the actions taken by NCI on its New York contract.

In June 1974, NCI awarded a $2.5 million contract to the New York State Department of Health to conduct cervical screening programs within the State. The contract called for the completion of the following nine tasks:

--Performing 212,600 Pap tests over a 3-year period.

--Notifying the women and/or their physicians of test results.

--Making efforts to assure that women with positive or suspicious test results return for retesting or other appropriate medical management.

--Assuring that a definite diagnosis is made for all women with positive or suspicious Pap tests.

--Emphasizing screening of low income or indigent women who have never had a Pap test.

--Attempting to rescreen women every 12 months during the life of the contract.

--Ensuring that every woman with cancer is given high-quality therapeutic and followup care immediately.

--Submitting to the contracting officer quarterly progress reports describing the program's progress in detail.

--Submitting an annual report to the contracting officer evaluating the overall program for that period and a brief summary of salient results of the program for the reporting period, except for the final six months of the contract, when a summary of the results achieved during the performance of the entire contract was to be submitted.

Seven of the nine tasks were not accomplished, although the contractor worked on all of them. Regarding the two remaining tasks, which required the contractor to notify women and/or their physicians of results of Pap tests and to make definite arrangements to ensure that women with cancer were given immediate, high-quality care, NCI's records were inadequate to allow us to determine whether they had been accomplished.

One of the required tasks was performing 212,600 Pap tests, which the contractor intended to do through 10 subcontractors in various parts of the State. While three of the subcontractors exceeded their test requirements, the other seven fell short by substantial margins. Of the 212,600 tests called for in the contract, the subcontractors performed only 61,008 (29 percent). In 1975 and 1976, the contractor terminated two subcontracts for 92,000 Pap tests because of the low level of testing done. These subcontractors were expected to do 43 percent of all the Pap tests required under the contract, but they completed only 4 percent (3,551 of the 92,000 tests planned).

In June 1976, the Cancer Control Intervention Programs Review Committee met for a merit review of the New York contract. The reviewers found a major problem with the level of tests performed. According to the reviewers, of 60,000 Pap tests planned for the first year of the contract, only 20,000 were performed. In addition, the reviewer's report said the "submission of patient information to NCI was totally unsatisfactory in that it is nonexistent." The report concluded that the contractor was noncompliant with contractual obligations. Most of the reviewers recommended that the contract be terminated.

DCCR decided to make a site visit to the project before making a final decision. The site visit was conducted in July 1976. The site visitors also recommended the project

be terminated, with the majority recommending a phaseout. One reason for this recommendation was the low number of screenings done. The Intervention Programs Review Committee met again in November 1976 for another review of the project, and unanimously recommended terminating the project. The Committee's recommendation was made because of deficiencies in screening quotas, unsatisfactory data management, and the inordinately high cost of screening. DCCR agreed with the Committee's recommendation. It modified the contract to reduce the screening requirement from 212,600 to 60,950 Pap tests, and reduced the estimated cost from $2.5 million to $1.5 million. Although work was phased out, portions of the contract were continued to the original completion date of June 1977. The Chief of the Control and Rehabilitation Contracts Section said that the reduction in the contract amount was determined by NCI through a standardized procedure whereby NCI reviewed contractor estimates of the costs to be incurred during the period in which the contract is being phased out. These costs were then added to the costs already incurred by the contractor and the contract amount was adjusted accordingly. The reduction in the contract did not relate to the contractor not fully accomplishing specific contract tasks.

We spoke with the DCCR project officer for this contract to determine how the information developed under the contract was used. He said that DCCR intended to use the information from this project along with information from 15 other cervical screening projects to broaden its data base for cervical screening. However, the data submitted by the contractor were unusable and were discarded.

We discussed monitoring with the project officer for the New York contract. He said DCCR officials decided that onsite monitoring would be held to a minimum because of the heavy workload of DCCR's project officers. In lieu of early onsite monitoring, the project officer said that monitoring was to be accomplished by merit review. In the case of the New York contract, merit review would be accomplished between January and June 1976. 1/ The effect of this was that the contractor would perform the contract for 1-1/2 to 2 years without onsite monitoring by the project officer.

DCCR relied on the contractor's quarterly and annual progress reports to monitor the contractor's performance. Because the reports were generally submitted by the individual

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1/As discussed on page 20, merit review occurred in June 1976.

subcontractors rather than the New York State Department of Health, it was difficult for NCI to assess the contractor's performance. However, many of the subcontractors' reports showed that the subcontractors had difficulty in performing the required number of Pap tests. DCCR did little to correct the problems identified in the progress reports. Not until after the merit review was conducted and the contractor's performance was found to be poor, did NCI decide to terminate the contract.

In commenting on our draft report, NCI stated that the contracts in question required the contractors to exert their "best effort" to achieve the requirements of the workscope and that there are many reasons why tasks are sometimes not achieved despite "best effort." NCI said that portions of the Louisville and Tyler contracts were predicated on the assumption that large numbers of tumors would develop in the exposed populations. According to NCI, the tumors never developed and the contractors, therefore, could not carry out all of the related tasks.

In our opinion, five of the six tasks which were not accomplished in the Louisville and Tyler contracts were not predicated on the development of tumors. For both contracts, the contractors were to gather and analyze data, and conduct employee health education programs. For the Louisville contract, former employees of a manufacturing plant were to be included in the research project. According to the project officers and the Cancer Control Merit Review Committee reports, these tasks were not fully accomplished. The Merit Review Committee also questioned whether the contractors exerted their best effort on some of the tasks. For the New York contract, NCI reported that the reason it terminated the contract was that the contractor was not exerting "best effort."

CONTRACTING PROBLEMS PREVIOUSLY IDENTIFIED

In the last 5 years there have been several reviews of NCI's contracting procedures. Some of these reviews included cancer control projects; others did not. Since all NCI contracting officer activities are centralized, any review of NCI contract officer activities could reflect on cancer control projects.

In August 1976, the staff of the House Committee on Interstate and Foreign Commerce issued a report on its investigation of NIH. In a section dealing with NIH's research contracts, the report stated:

> "Criticism of the contract mechanism focuses very much on the National Cancer Institute * * *. It is alleged that contracts * * * award and monitoring is highly affected by favoritism between the staff of the National Cancer Institute and specific investigators * * *. While the philosophical debate regarding the justifications for contracts versus grants is a hard one on which to gain agreement, there is agreement on the need for adequate monitoring by NIH staff to assure successful contract performance. The stringent restriction on staffing increases at NIH has made it difficult to adequately provide for contract management."

The report identified a need for further study of the issue regarding staffing needs for adequate contract monitoring.

In our February 10, 1978, report, "Need to Improve Administration of a Carcinogen Testing and Carcinogenesis Research Contract" (HRD-78-44), we pointed out that the project officer did not notify the contracting officer of certain matters that affected the scope of the work and the contracting officer did not attempt to enforce certain contract provisions. This report provided the impetus for an HEW Inspector General review of NCI's contracting operations.

The Inspector General's review included an examination of the cancer control program's procurement operations. The resulting May 1978 report stated that there was little evidence to show that program personnel monitored contractors' technical progress and made adjustments to correct poor performance. The report made several recommendations concerning contracting operations at NCI.

An action plan to correct contracting deficiencies noted in the Inspector General's report was prepared and approved for implementation in May 1978. Presently, the Inspector General's staff is following up on its report to determine how the action plan is being implemented and whether these actions have eliminated the previously reported contracting deficiencies at NCI. A report on this followup will be issued later this year.

APPENDIX II

The Surveys and Investigations Staff of the House Appropriations Committee issued a report in October 1978, including the results of a review of the largest contract awarded by NCI. In reporting its findings, the staff said that the most evident abuse of the Federal Procurement Regulations was NCI's failure to effectively administer the contract. Also, the report said that the contracting officer was being circumvented and that the responsibilities of the contracting and project officers had been subverted.

CONCLUSIONS

NCI's administration of five cancer control contracts we reviewed was inadequate. NCI failed to adhere to both its own and HEW procedures in awarding and managing the contracts. NCI substantially increased the amounts awarded for proposed contracts without properly revising project plans and failed to implement reviewers' recommendations on the technical aspects of contracts. Contractors did not perform tasks specified in the contracts, and project officers failed to bring problems to the attention of contracting officers so that corrective actions could be taken. In some instances, the workload of the project officers may have contributed to these problems.

Although our review was limited to five contracts, the HEW Inspector General found similar deficiencies in NCI's overall contract administration, and the Chairman of the Cancer Control Merit Review Committee stated that the deficiencies we found in the cancer control contracts were widespread.

NCI COMMENTS AND OUR EVALUATION

In a draft of our report, we recommended that the Secretary of HEW require the Inspector General to review NCI's administration of cancer control contracts to determine if the deficiencies we identified are widespread, and if so, the Secretary should require the Director, NCI, to develop a plan to correct such deficiencies. In commenting on our draft report, NCI stated that such a plan had already been developed and there was no need for the Inspector General to conduct a special review of cancer control contracts. We were not made aware of the action plan until after the draft report was submitted for comment. After reviewing it, we believe if it is adequately implemented, contracting weaknesses should be corrected. Since the Inspector General's staff is conducting a followup review of NCI contracting

actions, we have deleted our recommendation for a separate review by the Inspector General.

NCI stated that the five contracts we reviewed were only 1.5 percent of all contracts awarded between 1974 and 1979, and were not representative of current contracting practices and that substantial changes in contracting policies have been introduced. Further, NCI said that the contract administration problems we found represented failures of documentation rather than failures to follow prescribed review and implementation policies. Also, NCI stated that it is under no requirement to insist that contractors encourage or assist continuation of projects after Federal funds end. NCI believes, therefore, that contracting practices within DCCR meet the standards set by Federal requirements and are in compliance with the plan submitted by NCI to HEW to correct contracting problems.

We have not said that the five contracts we reviewed were representative of all cancer control contracts. But we did note that other reviewers have identified similar contracting problems. We disagree with NCI's opinion that the contracting problems we found were only documentation problems. As discussed in the report, NCI did not have adequate documentation for substantial increases for the costs of contracts--with the costs of two contracts being more than tripled over the costs approved by review groups--and NCI did not adhere to prescribed contracting procedures when justifying these increases. Further, NCI did not ensure that deficiencies in proposed contracts were corrected before the award of the contracts. Some of these deficiencies plagued the contracts during their entire life. Regarding the continuation of NCI's contracts after Federal funding ends, we did not state that NCI was under any requirement to do so. However, although NCI has stated it expects many of its contracts to be continued, it has never done a study to determine if the projects initiated under the contracts are continued when Federal funding ends and, consequently, does not know the extent to which successful demonstration projects are continued by localities after Federal funding ends.

STATUS OF FUNDS AND STAFF AVAILABLE TO THE CANCER CONTROL PROGRAM

Although adequate funds have been available for the cancer control program, hiring and retaining qualified professional staff has been difficult. According to program officials, salary limitations were the main reason for a shortage of professional staff. These officials believe that the shortage has hindered DCCR's administration of the cancer control program and contributed to the problems discussed in appendix II.

During fiscal years 1975-79 the proportions of NCI's total obligations and authorized staff designated for the cancer control program have remained relatively constant. In terms of actual dollars, however, the amount obligated for the cancer control program has increased 38 percent. During the same period, authorized positions have increased by 2 percent, but DCCR has been unable to fill all of its authorized positions. In fiscal year 1979, the program was operating at about 88 percent of its authorized strength. DCCR claims that all of the vacancies are for professional staff. To compensate for this shortage, DCCR has hired experts to help administer the program.

PROPORTION OF NCI FUNDS OBLIGATED FOR THE CANCER CONTROL PROGRAM HAS REMAINED RELATIVELY CONSTANT

From fiscal year 1975 through fiscal year 1979, NCI's obligations increased from $699 million to about $937 million--about 34 percent. During the same period, the amount obligated for the cancer control program increased from about $50 million to about $70 million--about 38 percent. For fiscal years 1975-79, the following table shows the NCI obligations and the amounts obligated for the cancer control program. The amounts in this table include operating expenses (salaries, wages, travel, etc.) and contract and grant costs.

Fiscal year	NCI obligations	Amount obligated for cancer control program	Percent of NCI obligations
	(000 omitted)		
1975	$ 699,000	$ 50,375	7.2
1976	761,450	56,806	7.5
1977	814,957	60,625	7.4
1978	872,369	64,355	7.4
1979	936,696	69,733	7.4
Total	$4,084,472	$301,894	

FILLING AUTHORIZED POSITIONS HAS BEEN ESPECIALLY DIFFICULT FOR PROFESSIONAL STAFF POSITIONS

Staff positions authorized for the cancer control program increased 23 percent from fiscal year 1975 through fiscal year 1977, leveled off in fiscal year 1978, and decreased 17 percent in fiscal year 1979. These changes have had only a marginal effect on the size of the professional staff administering the program because DCCR has not been able to hire and retain enough professional staff to fill authorized positions.

NCI's authorized personnel ceilings increased by 168 positions (about 9 percent) from fiscal year 1975 through fiscal year 1979. During this period, NCI increased DCCR's personnel ceiling by a net of one position (2 percent). The table below shows the personnel authorized for NCI, DCCR, and the percentage of NCI staff assigned to DCCR.

NCI and DCCR Authorized Personnel (note a)

Fiscal year	Personnel ceiling NCI	Personnel ceiling DCCR	Percent of NCI staff authorized for DCCR
1975	1,889	47	2.5
1976	1,955	49	2.5
1977	2,031	58	2.9
1978	2,042	58	2.8
1979	2,057	48	2.3

a/Full-time permanent staff only.

Over the last 5 fiscal years, about 2.6 percent of the positions authorized for NCI have been designated for the cancer control program. But, DCCR was unable to use all the authorized positions because it was unable to hire all the professional staff it needed. For example, in fiscal year 1979, DCCR was authorized 48 staff; at the end of the year, it had 42 persons on board and 6 vacancies. The former DCCR Director said that all of the vacancies were professional personnel. The table below shows DCCR's personnel on board at the end of fiscal years 1975-79, the total vacancies, and the estimated vacancies for professional personnel.

DCCR Personnel Status (note a)

Fiscal year	Personnel ceiling	On board at yearend		Total vacancies	Estimated professional vacancies
		Professional	Clerical		
1975	47	21	15	11	11
1976	49	19	22	8	8
1977	58	26	23	9	9
1978	58	27	19	12	12
1979	48	25	17	6	6

a/Full-time permanent staff only.

As the table shows, DCCR has never been able to fill all of its available positions. The former DCCR Director attributed the problem of hiring professionals to differences in salaries between the Federal and private sectors. For example, one specialty needed by DCCR is an oncologist (tumor specialist). An oncologist in the private sector, with the experience and expertise DCCR needs, would usually expect to earn between $50,000 and $100,000 per year, according to DCCR. Generally, the highest grade DCCR could offer an oncologist is a GS-14, which has a base salary of about $35,000 per year. Other specialties DCCR needed that were difficult to obtain because of salary problems were physical medicine, radiology, surgery, internal medicine, obstetrics and gynecology, community health, and otolaryngology (ear and throat specialist).

To fill its need for professional personnel, DCCR appointed experts who could be offered compensation more in line with their salaries in the private sector. The following table shows the number of experts hired to compensate for professional staff vacancies.

Fiscal year	Experts on board	Estimated professional staff vacancies
1975	10	11
1976	17	8
1977	11	9
1978	14	12
1979	9	6

CONCLUSIONS

During the last 5 fiscal years, NCI has increased the funds obligated for the cancer control program. However, the proportion of NCI's total obligations authorized for the program has remained about the same. Although NCI continued to authorize nearly the same proportion of its staff for the program in fiscal year 1979 as it did in fiscal year 1975, it increased the actual staff authorized for the program by only one position.

NCI has had difficulty in recruiting professionals for the cancer control program. As a result, DCCR had a net increase in its total professional staff of only four from fiscal years 1975 to 1979, even though its personnel ceilings would have allowed for substantially more staff. The problem in hiring professionals stems primarily from the differences in pay between the Federal and private sectors.

CANCER CONTROL PROGRAM ADVISORY GROUPS

NCI uses public advisory groups for assistance in its mission of preventing, curing, and controlling cancer. Six advisory groups advise the cancer control program--three provide policy advice and three provide technical advice on the scientific merit of projects.

Of the three policy advisory groups, the Cancer Control and Rehabilitation Advisory Committee has been the most active in making recommendations to improve the cancer control program. From fiscal years 1975 to 1979, the Committee made numerous recommendations, most of which DCCR implemented. The other two policy advisory groups--the President's Cancer Panel and the National Cancer Advisory Board--have provided little advice to the control program.

ADVISORY GROUPS

NCI is mandated to seek advice from public advisory groups to help it achieve its goal of preventing, curing, and controlling cancer. These groups are composed of individuals with scientific or clinical expertise, as well as leaders in such fields as education, law, social services, and public affairs.

As of July 1, 1979, NCI had 26 advisory groups, 6 of which provide advice to the cancer control program, according to a DCCR official. The six groups are the:

--President's Cancer Panel.

--National Cancer Advisory Board.

--Cancer Control and Rehabilitation Advisory Committee.

--Cancer Control Merit Review Committee.

--Cancer Control Grant Review Committee.

--Cancer Control Intervention Programs Review Committee.

The first three groups listed provide policy advice to DCCR on the cancer control program. The advice provided by these groups and DCCR's actions to implement their recommendations are discussed in the following sections. The Cancer Control Merit Review Committee and the Cancer Control Intervention

Programs Review Committee give DCCR advice on the technical merit of projects. DCCR's actions to implement their advice are discussed in appendix II. Since we did not make a detailed review of individual grant projects, we did not examine the actions of the Cancer Control Grant Review Committee.

ATTENTION GIVEN TO THE CANCER CONTROL PROGRAM

President's Cancer Panel

The President's Cancer Panel was established by the National Cancer Act of 1971. It is composed of three members appointed by the President. The panel's role is to advise the President on the development and execution of the National Cancer Program. In this role, the panel may influence the cancer control program, which is a part of the national program.

Our review of the minutes of the meetings, from fiscal years 1975 to 1979, showed that the panel discussed the cancer control program many times. However, most of the discussions consisted of briefings by DCCR officials on the program's activities. The panel made no specific recommendations in areas needing improvement or activities to be explored. According to the panel's former Chairman, the panel's role is to monitor the National Cancer Program. He believes that specific programmatic advice is more a function of DCCR's advisory groups, such as the Cancer Control and Rehabilitation Advisory Committee.

National Cancer Advisory Board

The National Cancer Advisory Board was also established by the National Cancer Act of 1971. It is composed of 29 members, 18 appointed by the President and 11 specified by

the act. 1/ The board's role is to review grants-in-aid relating to cancer research and to advise the NCI Director on the National Cancer Program. Thus, the board may influence the cancer control program.

We reviewed the minutes of the board's meetings from fiscal years 1975 to 1979. Our review indicated that the board never reviewed the entire cancer control program. In October 1975, the board reviewed a part of the control program--the community-based programs, which are designed to demonstrate and promote the implementation of cancer control methods in a community--and made five recommendations. According to the former DCCR Director, appropriate action was taken to implement these recommendations. The only other instances we found where the board addressed the control program occurred in 1977, when the NCI Director reported on breast cancer demonstration projects, and in 1978, when the Chairman of the Cancer Control and Rehabilitation Advisory Committee gave a report on a review it made of the control program for the board. The board made no recommendations based on these reports.

Cancer Control and Rehabilitation Advisory Committee

The NCI Director established the Cancer Control and Rehabilitation Advisory Committee in November 1974. The committee, authorized by section 410 of the Public Health Service Act (42 U.S.C. 286d), as amended by the National Cancer Act of 1971, consists of 20 members. Its role is to advise the NCI and DCCR Directors on matters relating to cancer control activities and on the coordination of the entire national effort to control cancer.

1/The members specified by the National Cancer Act of 1971, as amended by section 232 of the Community Mental Health Centers Act Amendments, are the Secretary of HEW; Director, Office of Science and Technology Policy; Director, NIH; Chief Medical Officer of the Veterans Administration; Director of the National Institute for Occupational Safety and Health; Director of the National Institute of Environmental Health Sciences; Secretary of Labor; Commissioner of the Food and Drug Administration; Administrator of the Environmental Protection Agency; Chairman of the Consumer Product Safety Commission; and a medical officer designated by the Secretary of Defense.

Our review of the committee's meetings from fiscal years 1975 to 1979 showed that it has been very active in providing advice to DCCR. During this period, the committee made 63 recommendations relating to the cancer control program. DCCR took action to implement 56 of the recommendations. For the remaining seven recommendations, we believe DCCR was either in the process of implementing the recommendations or had valid reasons for not implementing them.

CONCLUSIONS

Of the three policy advisory groups to the cancer control program, the Cancer Control and Rehabilitation Advisory Committee has provided most of the advice and recommendations to DCCR. DCCR has taken adequate action to implement the committee's recommendations.

APPENDIX V

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Congress of the United States

House of Representatives

Washington, D.C. 20515

March 1, 1979

The Honorable Elmer B. Staats
Comptroller General of the
United States
General Accounting Office
441 G. Street, N.W.
Washington, D.C. 20548

Dear Mr. Staats:

For some time now I have been particularly concerned about the National Cancer Institute's efforts to implement the cancer control program established by section 409 of the National Cancer Act of 1971. The act, as amended, authorizes NCI to establish and support demonstration, education, and other programs to control cancer. NCI's Division of Cancer Control and Rehabilitation has been given responsibility for implementing these activities.

A disturbing number of allegations have been brought to my attention that the cancer control program has not been very effective since few accomplishments have come out of the program. Also, questions have been raised about the operation and management of the program. Members of my staff have obtained information which indicates that there may indeed be some serious problems. Therefore, I would like your Office to make a comprehensive review of NCI's efforts to implement the cancer control program since 1974.

In conducting your review, would you please address the following issues:

1. What are the objectives of the cancer control program and how are they being implemented?

2. Have DCCR contracts resulted in the products called for? How frequently have contracts been discounted before planned completion, and what are the reasons for this occurring?

3. Are demonstration grants being continued by grantees after Federal funds cease? If not, has any action been taken to determine why this is happening?

4. What has been the rate of professional staff turnover? Is DCCR having a problem with filling professional staff vacancies?

In addition, please pursue any additional issues your staff believes to be significant that will be an aid in evaluating the effectiveness of DCCR's

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implementation of the cancer control program.

I would appreciate it if you could provide me with a final report on your work by February 1980. Please feel free to contact my staff at any time for further assistance or clarification of the matters contained in this letter. I appreciate your attention to this matter.

Sincerely yours,

David R. Obey
Member of Congress

DRO:cre

APPENDIX VI

NCI RESPONSE TO THE GAO REPORT ON THE CANCER CONTROL PROGRAM

Summary of Issues and NCI Response

This is a response to the undated draft of a proposed Report to Representative David R. Obey entitled "Cancer Control Program--The Congress Should Examine Its Objectives and HEW Should Investigate Its Contracting Practices," which was received by the National Cancer Institute (NCI) on February 11, 1980. On February 14, NCI staff had the opportunity to discuss this draft Report with the General Accounting Office (GAO) staff. This response summarizes points raised during those discussions and adds some additional information.

NCI disagrees with many of the interpretations, "facts" and conclusions, and all of the recommendations of the February 11 draft Report.

The Report states that the premises upon which the legislation establishing the Cancer Control Program was based were incorrect, that NCI has modified the mission of the program without fully explaining this to Congress, and that GAO therefore recommends that Congress redetermine what the objectives of the Cancer Control Program should be and what level of effort is needed to accomplish the Program's objectives.

NCI contends that the premises upon which the Cancer Control Program legislation was based were correct in 1971 and continue to be correct in 1980, that the mission of this Program has not been modified except at the specific direction of the Congress. Also, NCI contends that Congress, the President's Cancer Panel, the Presidentially appointed National Cancer Advisory Board, have been kept fully informed about this Program and its resources and, therefore, oversight hearings

are unnecessary. It should be noted that NCI proposes to increase the emphasis on applied prevention activities within the Cancer Control Program in future years. This will be a shift in emphasis within the mandate of Cancer Control but will not be a modification of mission.

The Report further stated that the five Cancer Control contracts reviewed revealed improper and weak administration in awarding and monitoring practices; that NCI did not include provisions in contracts requiring the contractor to encourage or assist localities to continue projects after Federal funding ceased; that the deficiencies in contract administration were believed not to be limited to the five contracts reviewed; and that, therefore, the Secretary of HEW should require the Inspector General to conduct a review of NCI's administration of Cancer Control contracts in order to determine if there are program-wide problems.

NCI contends that the five contracts reviewed by GAO represent approximately 1.5% of the Cancer Control contracts and that the contracts were not selected at random and cannot be taken as a representative sample; that these five contracts were initiated more than 4-1/2 years ago and therefore are not representative of recent or current contract practices; that there is no Federal rule or regulation that requires contractors to encourage or assist in the continuation of projects after Federal funding stops and therefore NCI does not include a provision to this effect in all demonstration project contracts; that any contract administration problems described are not representative of recent or current contract procedures and do not take into account either the large number of substantial changes in contracting practices that have

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been introduced in the past several years or rational explanations for situations that were described by the GAO as deficiencies: and that, therefore, there is no need for the Inspector General to conduct a special review of NCI's administration of Cancer Control contracts.

The Report also stated that staff available for the Cancer Control Program has not kept pace with increased program funding.

NCI agrees with this observation, but contends that it is representative of a larger NCI problem in which funding (including Cancer Control funding) has increased from $699 million to $937 million in the past 5 years, while authorized personnel ceilings have remained essentially level (1,889 to 1,915). This overall pattern, which was acknowledged in the GAO Report, causes problems for the entire National Cancer Program, not just for the Cancer Control Program.

The Report finally stated that the Division of Cancer Control and Rehabilitation, NCI, had acted to implement recommendations made by policy advisors.

NCI is pleased to acknowledge this observation.

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I. THE CANCER CONTROL PROGRAM WAS FOUNDED ON AN INCORRECT PREMISE and PROGRAM OFFICIALS AND ADVISORS AGREE THERE WEREN'T MANY UNUSED RESEARCH ADVANCES.

The GAO Report alleged that the Cancer Control Program was established "... to rapidly transfer cancer research advances to general medical use" and that "... the thinking of scientists and Congress was that serious delays existed in putting the advances into practice. Medical experts estimated that once these existing advances were put into use and all cancer patients received the same level of care, about 50% of all cancers could be cured. However, the premise that many advances existed but were not being used proved incorrect." The implication of this statement is either that scientists testifying before Congress were misinformed or that they intentially misrepresented the facts to Congress, but that in either case, Congress was misled and passed inappropriate legislation.

The statement projecting that "about 50% of all cancers could be cured" was quoted numerous times in the GAO Report. It is therefore important to provide the complete quotation from the Report of the National Panel of Consultants on the Conquest of Cancer, 1970. Recommendation 5 states, "The cure rate for cancer is gradually improving. In 1930 we were able to cure only about 1 case in 5; today we cure 1 case in 3; and it is estimated that the cure rate could be brought close to 1 case in 2 by a better application of knowledge which exists today, i.e.,

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detection at an earlier stage through the more widespread use of existing techniques (such as the Papanicolaou test for women and mammography), coupled with an extension to all citizens of the same quality of diagnosis and treatment now available at the best treatment centers." This statement is quite accurate and not misleading. The facts indicate that the cure rate of 33% in 1970 has improved to better than 40% in 1977 (the last year for which figures are available). Thus, the cure rate has been brought closer to 50% and there is no reason to believe that the cure rate will not continue to improve. It should be noted that this has been accomplished without "... an extension to all citizens of the same quality of diagnosis and treatment now available at the best treatment centers."

As further evidence that the information presented by the Panel of Consultants was appropriately cautious, it is worth quoting another portion of the report which appears on Page 150. "Because of these new possibilities, a number of different specific approaches are becoming recognized that make cancer control conceivable. The variety of these promising approaches affords confidence that at least some of them will prove successful. Present research cannot promise a single miraculous breakthrough. It is more likely to lead to progressive improvements over a number of years. Effective control will be achieved for increasing numbers of particular forms of cancer--as indeed it has already been for a few of them--before it will become a reality for all."

It also must clearly be stated that there were research advances available in 1971 that had not effectively been put into practice.

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As examples, one can cite the following:

Prevention. The research advance was the identification of cigarette smoking as a major cause of lung cancer. The effective application of that knowledge had not occurred in 1971 and, although progress has been made, considerably more must be done to decrease cigarette smoking now so that the 125,000 cancer deaths annually attributed to cigarette smoking can be decreased in the future.

Detection. The research advance was the development of exfoliative cytology which made possible early detection of cervical cancer. The effective application of that research advance had not occurred in 1971 and, although progress has been made since then, approximately 7,500 women still die each year from invasive carcinoma of the cervix, a disease whose incidence could be sharply curtailed.

These are just two of the advances to which the Panel of Consultants referred. The issue was not whether there were advances that weren't being used at all as was implied on Page 5 of the GAO Report. Rather, the issue was whether cancer could be controlled through better information dissemination and demonstration of research advances that were being applied, but being applied ineffectively. Congress acknowledged this issue in House Report 92-659, page 24 (1971) where the Report of the House Committee on Interstate and Foreign Commerce contains the following explanation of the Control Legislation: "Cancer Control Programs. The Committee was very disturbed to find in its study of the cancer problem that identifiable funding for cancer

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control programs ceased with Fiscal Year 1970, and that a number of the activities previously supported through these programs have in one way or another been terminated or allowed to lapse. Disease control programs in cancer and other areas have long been a part of the public health scene, and their importance is incontrovertible, for they are a means of bringing into general medical applications the most practical fruits of research in terms of improved methods of treatment and control. Especially when a major national effort is being mounted to develop new cancer knowledge, it seems ill advised if not irresponsible to eliminate any useful means for speeding that new knowledge to application for the benefit of the public." Further, the Committee Report states "Accordingly, in order that States and other public or nonprofit agencies can once again receive funding for cancer control activities, the Committee has inserted in its bill authority for the Director of the National Cancer Institute to "establish programs in the prevention, control, and eradication of cancer"; and has included specific authorizations to help make sure that these funds intended to help in the attack on cancer are not diverted."

NCI concludes, therefore, that Congress established cancer control legislation on correct premises, that there were research advances that required dissemination in 1971, that there are research advances that require dissemination in 1980 and we anticipate additional research advances that will require dissemination as long as there is a National Cancer Program.

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The GAO Report further alleged that the former director of DCCR, NCI, considered premature application of cancer technology a more significant problem than lags in transferring technology. The former director disagrees with this interpretation of her comments, which were only intended to indicate that premature or inappropriate application is also a problem and that the Cancer Control Program must address this problem to assure optimal and safe technology transfer.

The Report alleged that the "control program was modified to focus on supporting projects to prevent the premature application of technology and also to promote technology aimed at an early detection of cancer. Thus, NCI has adjusted the basic mission of the Cancer Control Program authorized by the Congress." NCI believes that the mission to foster technology transfer certainly implies that only appropriate technology should be transferred and that information disseminated to the public and the health profession must help them to distinguish appropriate from inappropriate technology. Congress has made this explicit in the amendments to the Community Mental Health Centers Act, 1978, where the Cancer Control legislation was significantly modified and where the legislation states in part: that "Programs established and supported under this section shall include: ... 2. the demonstration of and the education of health professionals in (A) effective methods for the early detection of cancer and the identification of individuals with high risks of developing cancer ... 3. the demonstration of new methods for the dissemination to the general public concerning the early detection and treatment of cancer

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and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment and control of cancer."

Moreoever, Congress affirmed its intention that "early detection of cancer" was mandated under the Cancer Control Program when it specifically amended the legislation in 1974 to state "The Director of the National Cancer Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer, including programs to provide appropriate trials of programs of routine exfoliative cytology tests conducted for the diagnosis of uterine cancer."

In summary, there has been no modification in the focus of the Cancer Control Program, and NCI has not adjusted the basic mission. Congress has been fully informed, as evidenced by discussions of the Control Program in the House Reports of 1971, House, Senate and Conference Reports of 1974, House and Senate Reports of 1977, and the House Report of 1978.

II. ADVISORS HAVE MIXED OPINIONS ON THE CANCER CONTROL PROGRAM AND ITS FUTURE.

The GAO discussed this matter with the former Chairmen of the President's Cancer Panel, the Cancer Control and Rehabilitation Advisory Committee, and the Cancer Control Merit Review Committee, and also with the current Chairmen of the National Cancer Advisory Board and the Cancer Control and Rehabilitation Advisory Committee. As indicated on page 7 of the GAO Report, the responses were supportive of the program and "4 of the 5 said the Cancer Control

Program was worthwhile and should be continued." One of these advisors, the former chairman of the Cancer Control Merit Review Committee is quoted in the report as saying that "... the program had accomplished little that the medical community would not have done anyway and had not increased the body of knowledge needed to control cancer." Subsequent conversations with the former Chairman indicate that what he intended to convey was that the control program focused on diagnostic and treatment procedures that were already being performed and that the program helped disseminate them more rapidly. He feels that for at least some of these procedures, dissemination would have happened anyway, "sooner or later." NCI contends that this statement confirms that the program was doing what it was supposed to do, namely, identifying effective diagnostic and treatment procedures and accelerating their dissemination into general medical application.

In response to a request for a listing of significant accomplishments of the program, NCI provided a list of 57 items, 4 of which were included in the GAO report. The items selected by GAO are not representative of the major program accomplishments.

III. CANCER CONTROL PROGRAM'S EFFECT HAS NEVER BEEN EVALUATED.

The program itself has been evaluated by the Cancer Control and Rehabilitation Advisory Committee and also by the National Cancer Advisory Board in 1978. The GAO Report is correct, however, in indicating that the Control Program's effect has not been evaluated. NCI maintains that the National Cancer Program is an integrated effort including

the Control Program and a quantitative evaluation of the impact on morbidity or mortality of one segment of the program is not possible without considering the entire program. For example, a decrease in mortality from lung cancer could result from decreased incidence due to decreased smoking attributable to the Control Program, and/or from earlier diagnosis due to improved cytology techniques developed by the Diagnosis Program of the Division of Cancer Biology Diagnosis, and/or improved chemotherapy or radiotherapy developed by the Division of Cancer Treatment program. It is almost impossible to single out a segment of the NCP and evaluate the effectiveness of its efforts to reduce morbidity and/or mortality without evaluating the entire NCP.

CONCLUSION

NCI contends that:

- Congress authorized the Cancer Control Program to accomplish an appropriate objective.
- Congress has supplied resources appropriate to this objective.
- NCI has used the resources to address that objective.
- NCI has not used the resources to address objectives other than those authorized by Congress.

Congress has periodically and systematically exercised its right to be informed concerning the past performance and future direction of the Cancer Control Program.

NCI considers, therefore, that there is no need for Congress to hold additional hearings to again decide on objectives of the Cancer Control Program or the level of effort needed to accomplish those objectives.

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The main thrust of this enclosure of the GAO Report is that the NCI Research Contracts Branch and Division of Cancer Control and Rehabilitation have performed poorly with regard to initiation and management of contracts and that this performance was so poor that the Inspector General should conduct a complete review of NCI administration of cancer control contracts.

This sweeping conclusion was based on a review of 5 contracts--2 selected by Mr. Obey, 3 presumably selected at random. Between 1974 and 1979, 325 contracts were initiated in DCCR. The sample surveyed represents, therefore, 1.5% of the contracts initiated in the Division. Moreover, all of these contracts were initiated in or before 1975, while about 1/3 of the DCCR contracts have been initiated in 1976 or later. The sample is thus not only small, but also not representative of current, or even recent, practices. Based on a review of this inadequate and nonrepresentative sample, numerous serious allegations are made. NCI believes these allegations to be based at least in part on errors of fact and/or interpretation.

I. NCI PRACTICES IN AWARDING SOME CANCER CONTROL CONTRACTS HAVE BEEN IMPROPER OR UNSOUND.

The GAO Report alleged that DCCR failed to adhere to proper procedures in awarding 3 of the 5 reviewed contracts.

PROJECT PLAN REVIEWS NOT PROPERLY MADE.

Specifically, it alleged that, in the case of the University of Arizona, DCCR failed to review the project plan for relevance, need, and priority. In fact, this contract was one of 27 breast

cancer detection projects initiated in the Division of Cancer Biology and Diagnosis in 1973 and 1974, and subsequently transferred to DCCR in July 1976. DCCR therefore could not have carried out the review for relevance, need, and priority, since the contract was initiated in another division of the Institute. Furthermore, the contract with the University of Arizona was part of a larger program known as the Breast Cancer Detection Demonstration Projects. The entire program was reviewed for need and relevance by the Diagnostic Research Advisory Group on December 21, 1972, and documentation to that effect was supplied to the GAO on February 14, 1980.

The GAO Report also alleged that DCCR failed to review the project plan for relevance, need, and priority for a contract with the Illinois Cancer Council. NCI disagrees with this allegation. The contract record contains an approved Project Plan. This Plan contains a statement of relevance, need, and priority. The Plan also identifies the committee that reviewed the Project Plan and the date of the committee meeting. The Project Plan was signed by all the appropriate responsible officials. DCCR therefore did review the Project Plan, and the Project Plan itself contains the evidence. It is true that there are no minutes to document the meeting of the committee that reviewed the project plan, but at the time of that meeting, there was no policy requiring the preparation of such minutes. Subsequent procedures, developed within DCCR, established a system of minutes for these meetings and this procedure has been followed since that time.

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The GAO Report further stated that, in the case of the New York State Department of Health contract, NCI used an unchartered committee to review the proposal. GAO indicated that this was an incorrect procedure, since NCI's Committee Management Procedures and Guidelines state that ad hoc groups called together to give group advice or act as advisory committees should be chartered. The governing phrase, however, is "to give group advice." The ad hoc review group did not function to give group advice and did not reach a consensus. Rather, individual opinions (votes) were provided which were used by the Executive Secretary to prepare the Review Summary Sheet. The use of ad hoc consultants meeting as an unchartered group is a well-recognized NIH procedure, and is reaffirmed in NIH Instruction and Information Memorandum No. OD 78-2 "Implementation of PHS Peer Review Regulations--42CFR52h Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects." The only restriction is that the group should not function to reach a consensus but should provide individual opinions. The ad hoc group reviewing the New York State contract met that criterion and, therefore, the conclusion reached by GAO that the committee should have been chartered is not correct according to NIH policies. There may, however, be a discrepancy between NIH policy and the statement in NCI's Committee Management Procedures and Guidelines, since the latter were developed in April 1973 and have never been updated.

In additional questions concerning the review of this particular proposal, GAO asked why DCCP had not used the Cancer Control Prevention Detection Review Committee (a chartered review committee)

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rather than the ad hoc unchartered committee. The answer is that although this committee's charter was issued in January 1974, it took many months until committee members could be appointed and cleared through all of the Committee Management procedures and that because of this, the committee was nonfunctional at the time of the review.

II. PROCEDURES REQUIRING REVISED PROJECT PLANS NOT FOLLOWED.

The GAO Report alleged that in the case of the contract with the University of Louisville, NCI should have prepared a revision to the original Project Plan, since the Project Plan estimated costs at $880,000, while the amount negotiated with the University of Louisville was $2.8 million. The GAO is correct; under these circumstances a revision is required. NCI contends, however, that this revision was accomplished and documented in the form of a Source Selection sheet, which provided the documentation for the review that, among other things, approved the increase in costs from that amount estimated at the time of the preparation of the Project Plan to that amount determined to be needed after review of the responses to the RFP. The responsible officials, with the exception of the former Director, DCCR, who was out of the country, attended the selection panel meeting. The documentation for that meeting, the Source Selection sheet, was signed several days later by all of the appropriate officials, including the former Director. This sequence of events accounts for the inability of the former Director to remember exactly what happened. In any event, the Source Selection sheet was signed and, had that Source Selection sheet been completely filled out, NCI's procedures

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would have been correct. There was an error, however, in that the portion of the Source Selection sheet specifying costs was left blank. Thus, although the revision of cost estimate was reviewed and approved, and although all individuals involved in the review and approval knew the specific costs, (these costs were specified on the Summary Statement reviewed by this group), the certifying document was incompletely filled out. NCI agrees, therefore, that in this instance, there was a clerical error, but does not agree that NCI failed to follow the procedures for revising project plans.

The GAO Report also alleged that in the case of the contract with New York State, proper procedures for revising the project plan were not followed. NCI contends that this is an incorrect conclusion. In this instance, the Review Summary Sheet was prepared for 15 cervical cancer screening contracts. The revision for New York State was documented within the Review Summary Sheeet that covered the entire set of projects. This information was supplied to the GAO on February 14, 1980.

Another alleged deficiency concerns the modification to an existing contract. The particular contract cited was with the Texas Chest Foundation/East Texas Chest Hospital in Tyler, Texas. The GAO Report indicates that Modification 3 of this contract was accomplished without an appropriate amendment to the Project Plan. NCI contends that there must have been a Project Plan Amendment for Modification 3, since the Project Plan Amendment is referred to on Block C of the Review Summary Sheet (NIH-2042-3) and the contract file index (NIH-1313). The

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GAO is correct in indicating, however, that the Project Plan modification itself is missing. Thus, although NCI is confident that the proper procedure was followed and although there is corroborating evidence to substantiate this, the key document is missing. NCI notes that this particular contract file has been repeatedly entered by non-NCI personnel due to litigation concerning this contract and that maintenance of the integrity of this file has been difficult.

III. NCI HAS FAILED TO CORRECT DEFICIENCIES FOUND BY PRE-AWARD REVIEW GROUPS.

The GAO Report states that "our review showed that in 2 of the 5 contracts these groups (pre-award review groups) identified many problems in the proposed contracts and made 9 recommendations to correct the problems. However, we found no evidence that DCCR took any action to implement the recommendations prior to award of the contracts." In the Report, 6 of the alleged deficiencies are not further identified and only 3 problems from the contract with the University of Louisville are cited. NCI can only respond to those 3 particular problems, which were: 1) the absence of an individual to conduct the health education program for plant workers and their families of the hazards of vinyl/polyvinyl chloride; 2) the lack of coordination and cooperation among various parties in the program, and 3) the lack of a system for locating approximately 1500 former plant employees. NCI agrees that these deficiencies were not corrected before the award of the contract and that they should have been corrected.

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It should be noted, however, that the health educator was hired 3 months after the initiation of the contract and, as the GAO Report states, the coordination problem was later resolved. The issue of locating former plant employees was never successfully addressed. NCI notes again, however, that this failure to correct pre-award deficiencies is an example of contracting practices that occurred in 1974 and 1975 and that these practices have been corrected in subsequent years.

IV. ASSURANCES NOT OBTAINED FOR CONTINUATION OF SUCCESSFUL PROJECTS. There are two points that must be addressed with regard to this section of the Report. The first is that GAO has concluded that it would be desirable to obtain assurances from contractors for continuation of successful projects. NCI contends that there is NO Federal requirement to do this and that NCI should therefore not be criticized.

The second issue concerns what NCI told the Congress with regard to this matter. The GAO correctly quoted NCI materials submitted for the 1977 Senate Appropriation hearings in which NCI indicated that Cancer Control contracts are expected to ensure means of self-support following completion of the contract period. It must be pointed out, however, that this information was submitted 2-3 years after the initiation of the 5 contracts that were reviewed by GAO. These contracts, therefore, cannot be held to NCI's statement of 1977.

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and referred to in the GAO report, were not real problems. NCI believes that the issues raised by GAO were addressed in that memorandum, that there is good evidence that this contract was adequately monitored and that NCI did implement appropriate recommendations of post award review groups.

A list of 30 recommendations concerning the contract at Tyler/Texas was identified by GAO. For each "recommendation" the project officer, in a memorandum dated December 28, 1979, provided an explanation of what was done as a consequence of the recommendation. This memorandum addressed each of the issues raised by GAO. An additional 12 problems concerning the contract with the University of Louisville were noted by GAO and responded to on August 2, 1979. The attachments to that memorandum provide the available documentation relevant to the points raised by GAO.

Review of all of these documents confirms that in almost all cases, issues raised by the Merit Peer Review Committee or site visit teams were brought to the attention of the Principal Investigator and that there was sufficent follow-up on the part of NCI to determine that the contractor was taking steps necessary to correct those deficiencies that NCI desired to have corrected. (The Merit Peer Review Committee and site visit teams are advisory: NCI is not compelled to accept all of their recommendations.) However, NCI agrees that the records are not well documented in terms of specific directions from the Project Officer to the Contractor. It must again be noted that this was more a failure of documentation than a failure to obtain the desired result and again, that this reflects practices of the early days of this program, rather than current practices.

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Subsequent to the 1977 Senate Appropriation Hearings, discussions between DCCR staff and NCI contract officers revealed numerous problems with contractual attempts to assure continued funding of demonstration projects. One example of such a problem is that obtaining funding for continuation of a project may require fundraising. This is an unallowable cost under Chapter 15 of the Federal Procurement Regulations. Accordingly, present policy does not require that demonstration or other projects ensure means of self-support following completion of Federal funding.

In summary, DCCR has not attempted to routinely obtain contractual assurances that projects will be continued by local communities, and DCCR believes that such a policy would be inappropriate and may be legally unenforceable.

V. NCI HAS NOT ADEQUATELY MONITORED CANCER CONTROL CONTRACTS. NCI HAS FAILED TO IMPLEMENT RECOMMENDATIONS OF POST AWARD REVIEW GROUPS.

The Report stated that for 3 of the 5 contracts reviewed, the review groups identified 52 problems and made 43 recommendations to DCCR. The Report found no indication that NCI ever directed the contractors to implement the reviewers' recommendations. One of the 3 contracts referred to was with the Illinois Cancer Council. On January 2, 1980, the former project officer for this contract, sent a memorandum to the GAO refuting the allegations about failure of NCI to implement the one recommendation made by the Merit Peer Review Committee and providing information as to why the 6 "problems", identified by the Merit Peer Review Committee

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alleged any "failures" since that time. Moreover, there are many documented examples of such cooperation, and one such example, the operational memoranda, which were cosigned by the Contracting Officer and Project Officer were standard in the management of the 27 Breast Cancer Detection Demonstration Project contracts, is attached. 1/

The Report stated that ". . .the large caseload of both grants and contracts assigned to some project officers may have contributed to the lack of cooperation and coordination." The work required to monitor a grant is very much less than that required to serve as project officer for a contract. The Report information was therefore misleading when it lumped grants and contracts and stated that the ". . .caseloads vary from 3 to 44 projects. . ." since the individual with 44 projects was, in fact, project officer on only 19 contracts.

It should further be noted that in those instances where individuals were project officers on a large number of contracts, such as the 29 (not 30) attributed to the Branch Chief, the contracts were part of a program and each contract supported identical activities at different locations. An example would be the 27 Breast Cancer Detection Demonstration Projects. The amount of work required to monitor these 27 contracts is very much less than that needed to monitor 27 contracts, each with a different scope of work.

VII. NCI HAS NOT REQUIRED CONTRACTORS TO COMPLETE REQUIRED TASKS.

NCI rejects this allegation and wishes to point out that the contracts in question were "best effort" contracts where the

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1/GAO note: The memoranda referred to were examples of cooperation from the project office responsible for administering breast cancer demonstration projects.

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It is also worth noting that the former Chairman of the Cancer Control Merit Review Committee indicated in a telephone conversation that he does not think that he stated that his committee found "that DCCR apparently does little to implement the recommendations made by review groups" (bottom of page 22 and top of page 23 of GAO draft report). In fact, the former chairman indicated that his committee never received any information concerning the implementation of their recommendations and therefore had little basis upon which to evaluate this matter. He indicated that this lack of information was a source of frustration, but also indicated that neither he nor the committee had ever formally requested such follow-up.

VI. THERE WAS A LACK OF COOPERATION BETWEEN PROJECT OFFICERS IN DCCR AND THE NCI CONTRACTING OFFICERS.

The Report attributed to the Chief of the Cancer Control and Rehabilitation Contract Section the statement that there was "a lack of cooperation between the projects officers in DCCR and the NCI contracting officers." The Section Chief believes that this statement was taken somewhat out of context in that he indicated that there had been a lack of cooperation early in the program (5 years ago), but that this had been recognized and that a series of procedures had been instituted to assure proper cooperation. Some of these mechanisms are listed on page 26 of the GAO draft Report. The Report acknowledged the mechanisms but concluded that "apparently they did not work." NCI feels this is an unjustified conclusion since the "failures of cooperation" occurred before the mechanisms were established and GAO has not

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contractor is required only to exert best effort to achieve the requirements of the workscope. There are many reasons why tasks are sometimes not achieved despite "best effort." For example, portions of the Louisville and Tyler/Texas contracts were predicated on the assumption that large numbers of tumors would develop in the exposed populations. The tumors never developed; the contractor therefore could not carry out all of the related tasks.

When NCI determines that best effort is not being exerted, contracts are terminated. This is precisely what happened with the New York State contract, as documented on page 30 and 31 of the GAO Report. It should be noted incidentally that in the termination of that contract, costs were reduced by $1 million. The GAO Report incorrectly states that "no records were available to show how the $1 million reduction was determined." There is a standard procedure for making this determination and the documentation is available.

CONCLUSION

NCI contends that:

- The 5 contracts selected for review by GAO represent only 1.5% of the 325 Cancer Control contracts.
- The contracts were not selected at random, with 2 preselected by Mr. Obey, and all 5 having been initiated more than 4-1/2 years ago. These contracts are therefore not representative of current contracting practices.
- NCI was under no requirement to insist that contractors encourage or assist continuation of projects after Federal funding stops.

APPENDIX VI

- Contract administration problems identified by the GAO in general represented failures of documentation rather than failures to follow prescribed review and implementation policies.
- Contract administration problems described by the GAO occurred many years ago and are not representative of current contracting practices.
- Substantial changes in contracting practices have been introduced in the past several years.

NCI believes, therefore, that contracting practices within DCCR meet the standards set by Federal requirements and are in compliance with the plan submitted by NCI to the Assistant Secretary for Management and Budget as follow up to the 1978 reports by the Inspector General on NCI contract operations. It should be noted that GAO was unaware of this plan, or of the corrective actions taken in fulfillment of the plan, until February 14, 1980. Having seen the plan, GAO informed NCI that it would reconsider its recommendation that NCI contract operations be reviewed again by the Inspector General of HEW.

APPENDIX VI

The draft report states, on page 42, that Experts were not used as project officers before Fiscal Year 1979 and that they were then assigned only 2% of the caseload. In fact, Experts have served as project officers since 1974 and have borne a significant portion of the total caseload of contracts during that period. Confusion over this point apparently arose because GAO only inquired about currently employed Experts who served as project officers.

APPENDIX VI

The draft report cites, on page 46, the Interagency Coordinating Committee for Cancer Control and Rehabilitation as a DCCR advisory committee. It has been orally pointed out to GAO staff that this committee, during its brief existence, was not an advisory group, but rather was a coordinating group.